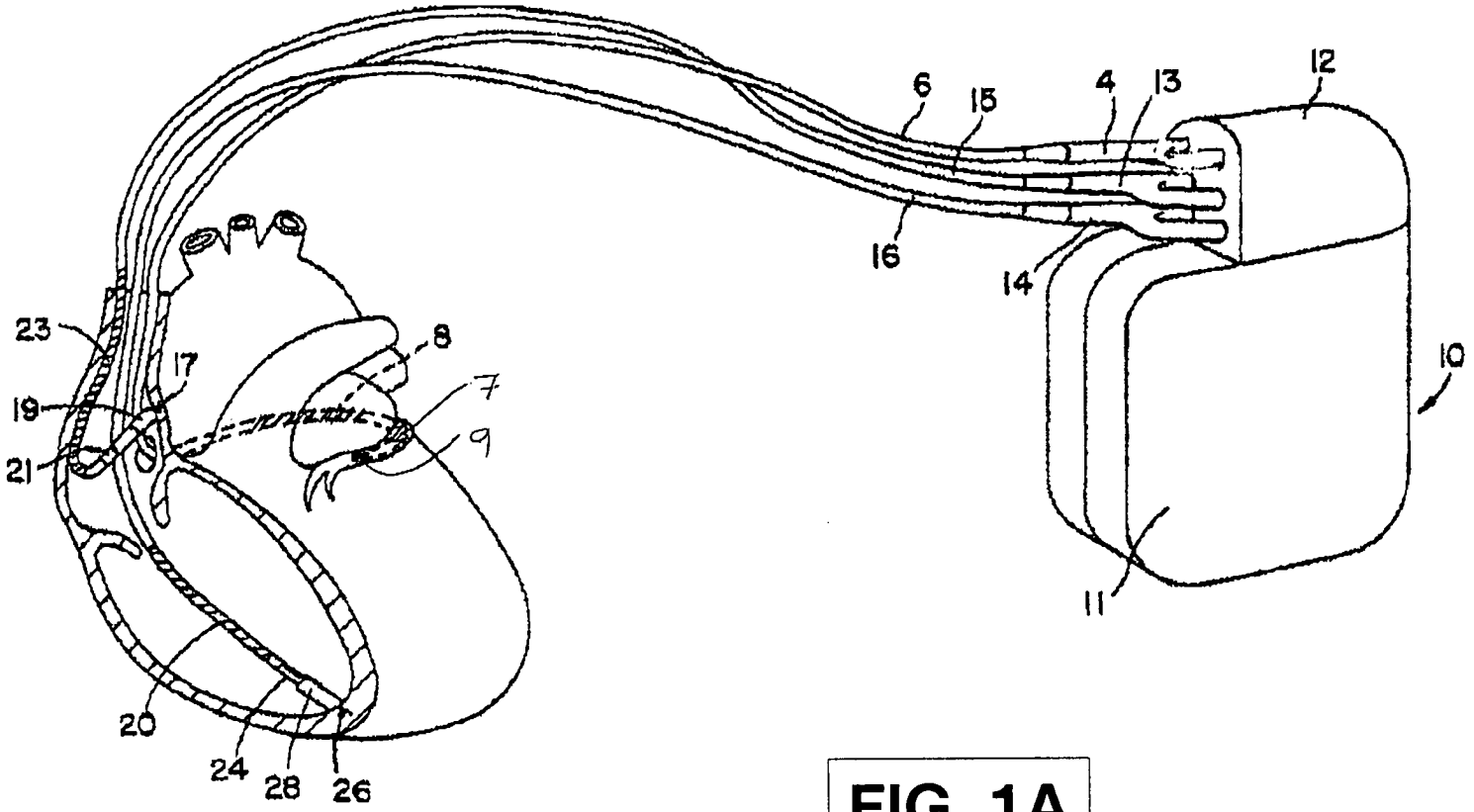


FIG. 1A

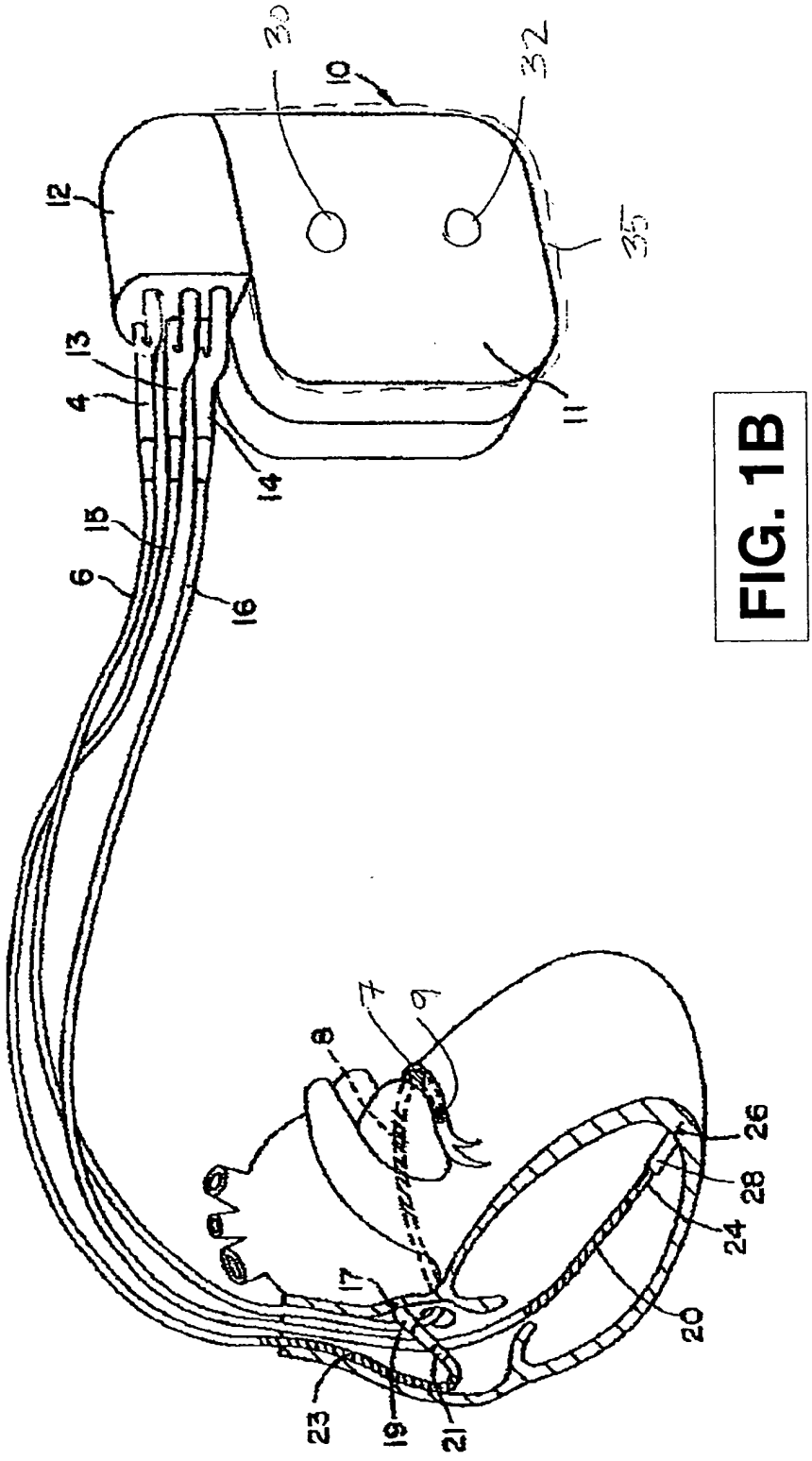


FIG. 1B

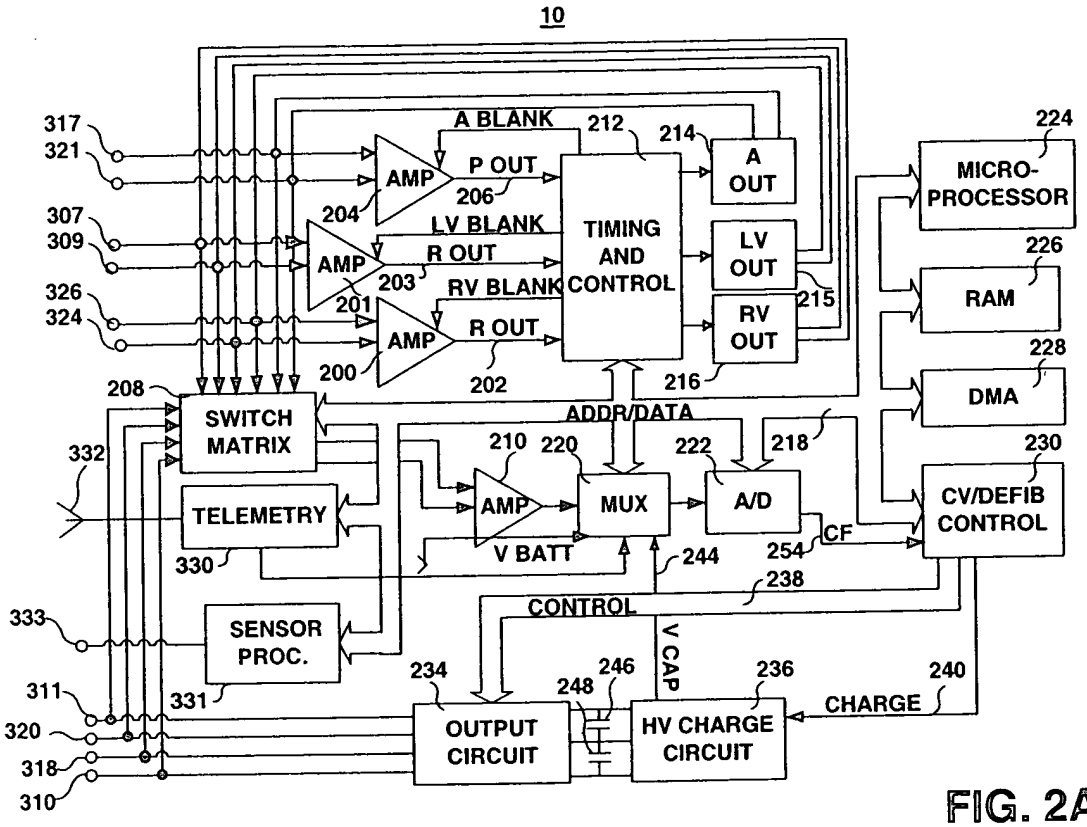

10
317
321
307
309
326
324
A BLANK
212
214
224
AMP
P OUT
206
A OUT
MICRO-PROCESSOR
204
LV BLANK
TIMING AND CONTROL
LV OUT
226
AMP
R OUT
203
RAM
RV BLANK
215
201
AMP
R OUT
RV OUT
228
200
202
216
208
DMA
SWITCH MATRIX
ADDR/DATA
210
220
222
218
230
332
AMP
MUX
A/D
CV/DEFIB CONTROL
TELEMETRY
CF
V BATT
254
330
244
238
CONTROL
333
SENSOR PROC.
V CAP
234
246
236
240
311
248
331
CHARGE
320
OUTPUT CIRCUIT
HV CHARGE CIRCUIT
318
310

FIG. 2A

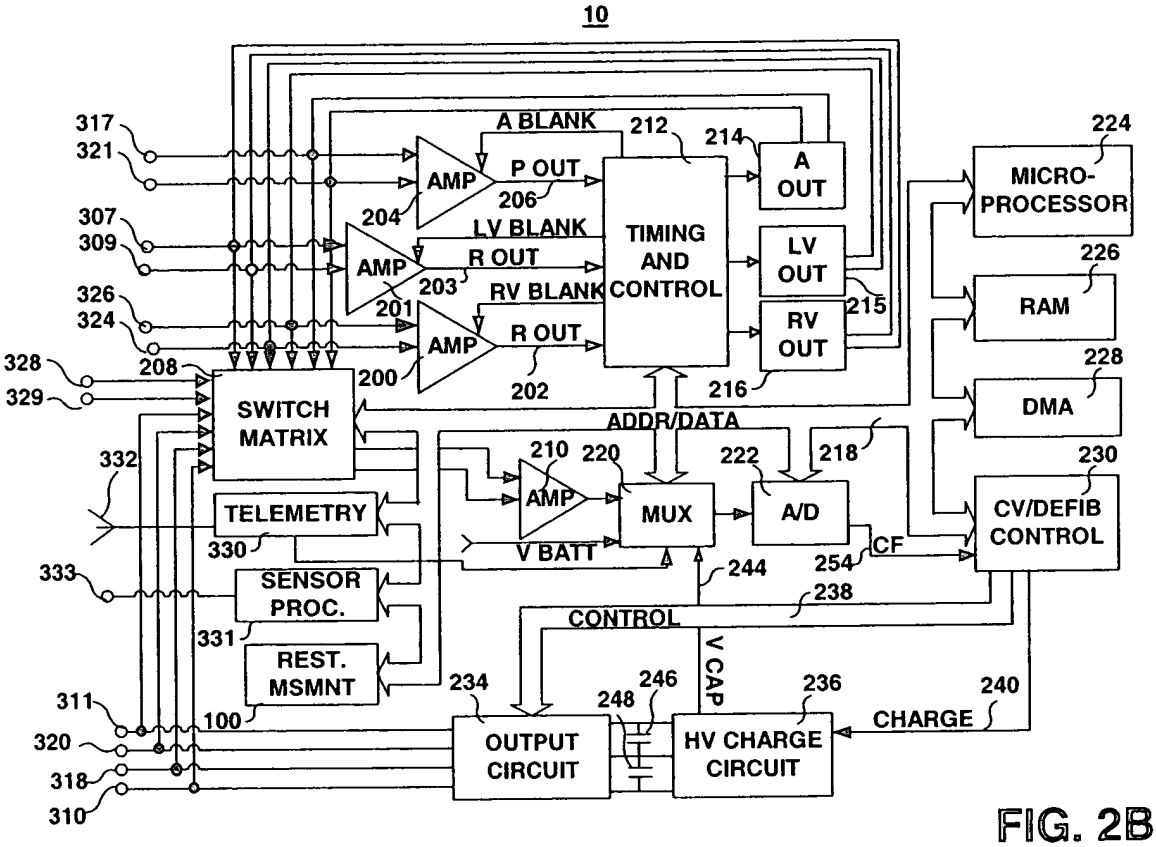

10
317
321
307
309
326
324
328
329
332
333
311
320
318
310
AMP
AMP
AMP
A BLANK
P OUT
LV BLANK
R OUT
RV BLANK
R OUT
TIMING AND CONTROL
A OUT
LV OUT
RV OUT
MICRO-PROCESSOR
RAM
DMA
CV/DEFIB CONTROL
SWITCH MATRIX
TELEMETRY
SENSOR PROC.
REST. MSMNT
ADDR/DATA
AMP
MUX
A/D
V BATT
CF
CONTROL
V CAP
OUTPUT CIRCUIT
HV CHARGE CIRCUIT
CHARGE
100
200
201
202
203
204
206
208
210
212
214
215
216
218
220
222
224
226
228
230
234
236
238
240
244
246
248
254

FIG. 2B

FIG. 3

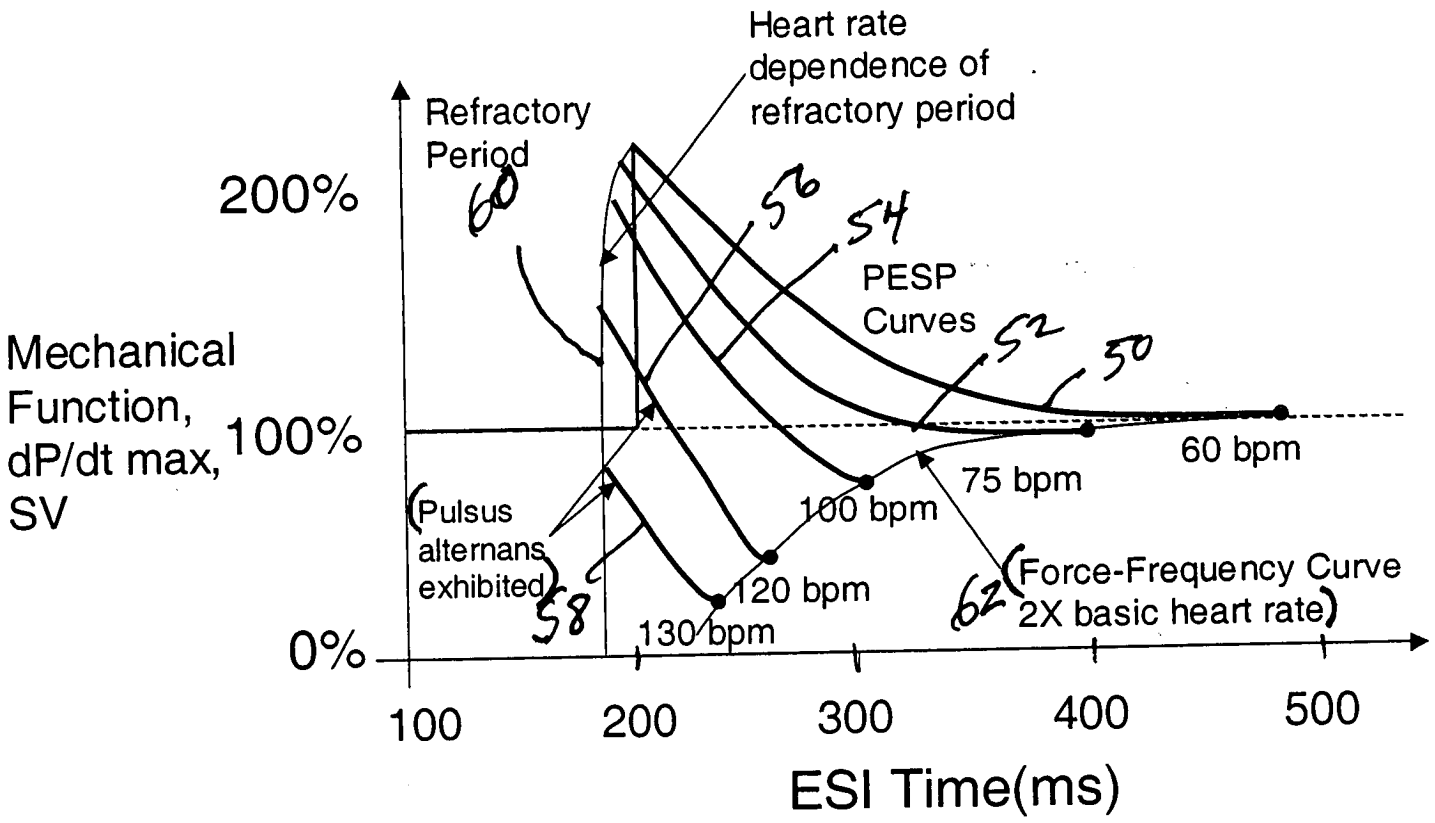
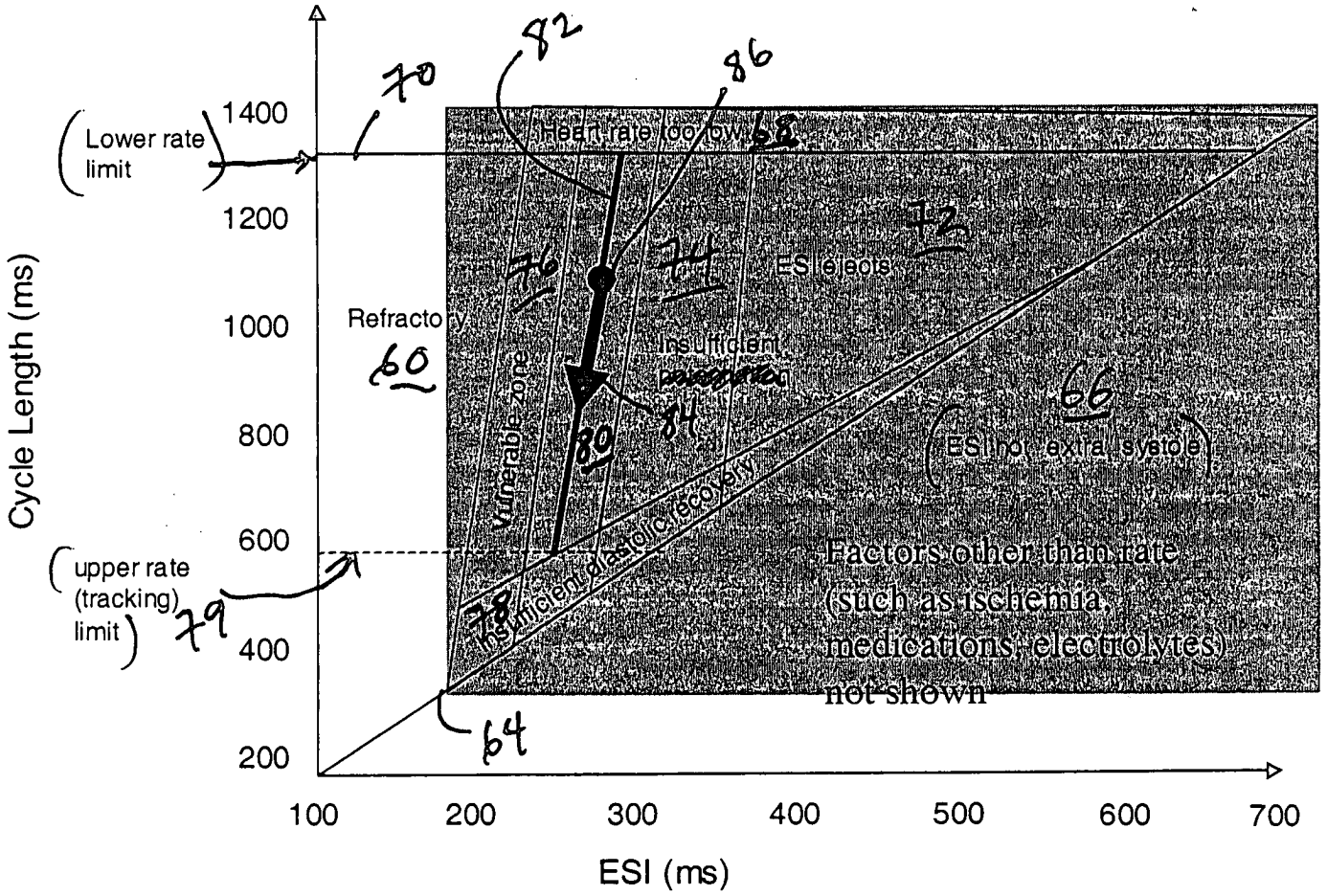
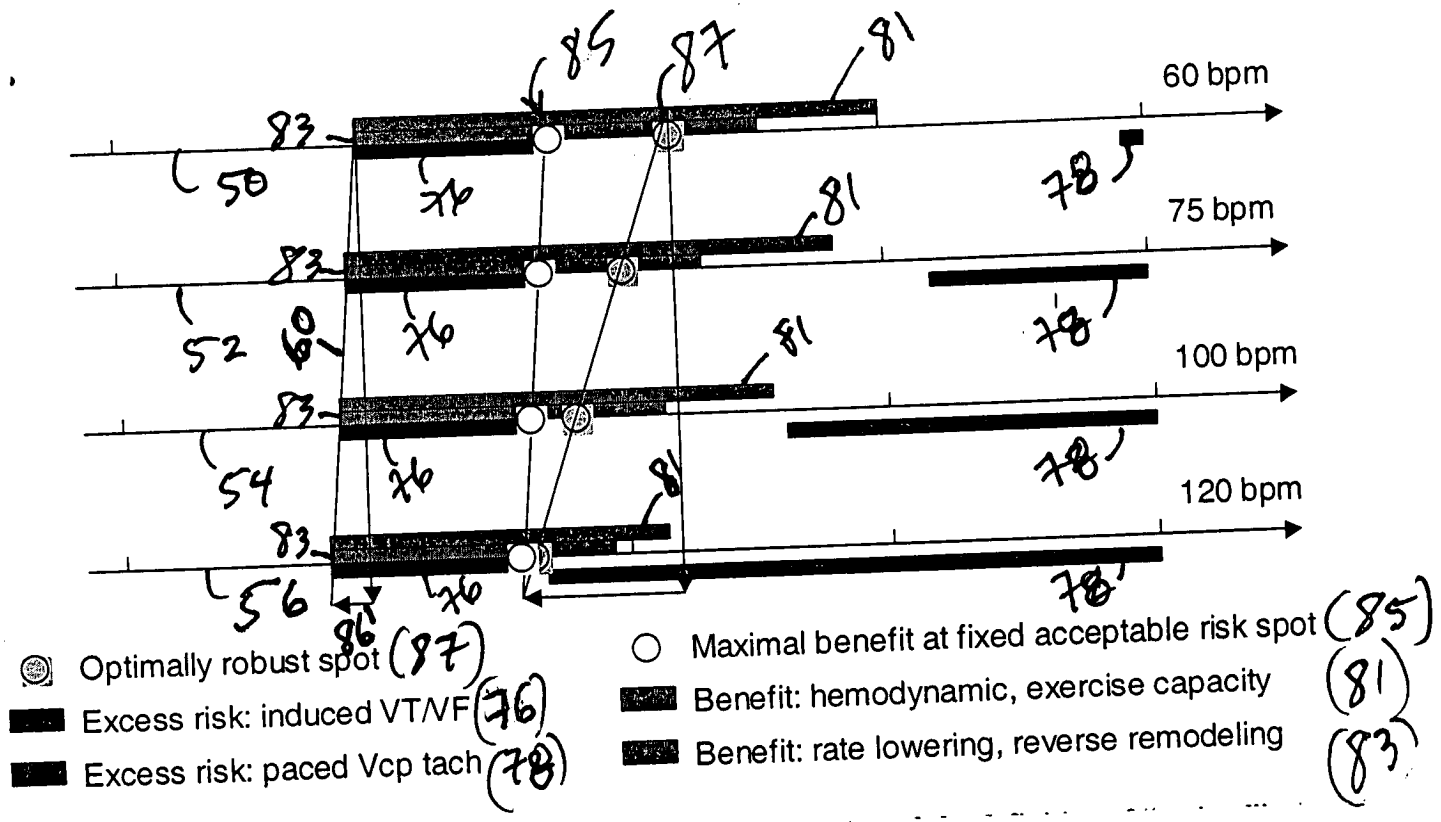

Heart rate
dependence of
refractory period
Refractory
Period
60
56
54
PESP
Curves
52
50
200%
Mechanical
Function,
dP/dt max,
SV
100%
60 bpm
75 bpm
100 bpm
120 bpm
130 bpm
(Pulsus
alternans
exhibited)
58
62
(Force-Frequency Curve
2X basic heart rate)
0%
100
200
300
400
500
ESI Time(ms)

FIG. 4


Cycle Length (ms)
1400
1200
1000
800
600
400
200
Lower rate limit
upper rate (tracking) limit
Refractory
Heart rate too low
ESI ejects
Insufficient prematurity
Vulnerable zone
Insufficient diastolic recovery
ESI not extra systole
Factors other than rate (such as ischemia, medications, electrolytes) not shown
100
200
300
400
500
600
700
ESI (ms)
70
82
86
72
76
74
60
80
84
66
78
64
79

Optimal ESI Timing and Heart Rate

FIG. 5



VT Detection

FIG. 6

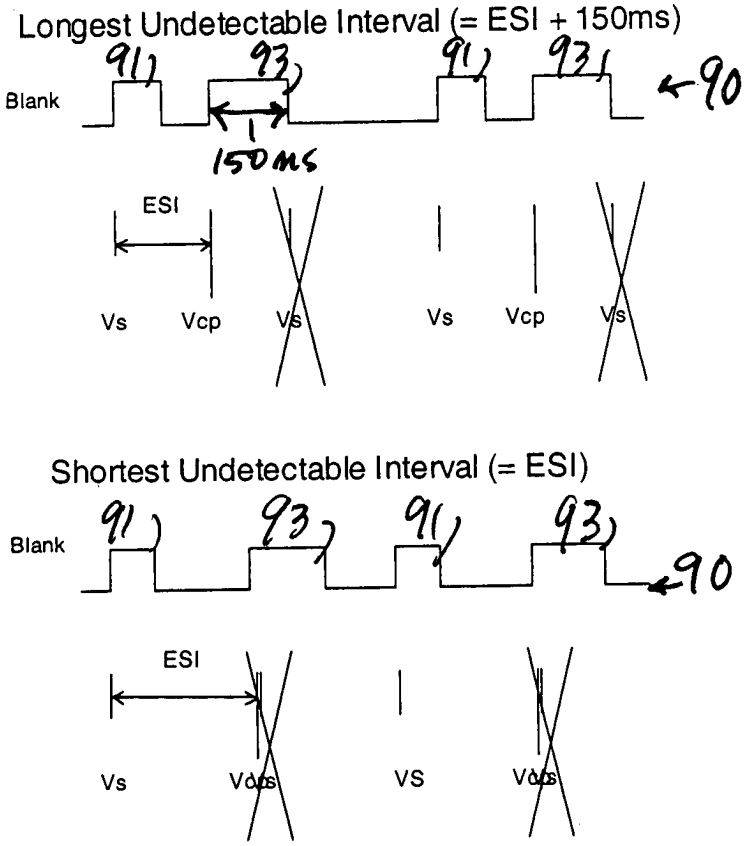


FIG. 7

Proposed Solutions

- Periodically drop ESS
  - Implementation of M of M+1 reveals VT after median delay of M/2 ESS cycles
  - Investigate reducing M at higher rates
  - Consider M = infinity (always on) if rate low enough. (M=0, always off, is already achieved at high rates via ESS rate limit safety rule.)
  - Can speed detection of VTs that are not 2:1 but are close and start with a phase that would otherwise delay their detection
- Suspend ESS upon inappropriate Asense timing
  - Safety rule engages with loss of AV synchrony during most VTs
- Dither timing of A-A or A-V intervals through A or V pacing
  - Occasional variations of 50-100 ms either way (if blanking is short) may be sufficient to enable hidden VT detection
- Auxiliary sensing vector
  - Use Coil-to-Can or other low polarization EGM signals to detect Vsense in blanking window
  - Discriminate by time or morphology from expected CPT evoked response
- Look for rate irregularity as a clue to hidden VT
  - As VT rate enters/leaves undetectable VT zone, CPT rate will abruptly halve/double (perhaps exceeding upper rate limit)
- Reduce blanking/refractory
  - Moves left hand limit to the right (see diagram)
  - Incomplete solution by itself, since Vcp is intended to cause a prompt depolarization which needs to be blanked
  - Perhaps complete solution if implement electronic blanking of known time/morphology evoked R waves but not VTs (see auxiliary sensing vector note)
  - Two fold increase of change of R-R interval at base mechanical rate per change of blanking significantly adds to heart rate range over which VTs can be detected without dropping ESS beats
  - In principle, atrial cross chamber blanking can be made short enough (a few ms) to never hide a VT
  - Could be accomplished with low polarization leads or sense amp electronics modifications.
  - May be combined with auxiliary sensing vector solution
- Deliver ESS with short ESI
  - Enhances window for VT detection (particularly at low ESS rates)
- Keep ESS upper rate limit low
  - Caps aliased VT rates. Upper limit 75 bpm makes all VTs faster than nominal VTDI detectable
  - Exploit in conjunction with reducing blanking and short ESIs (see above) to be least restrictive
  - Use an appropriately lower rate limit if Vpacing and not Vsensing to account for propagation differences

FIG. 8

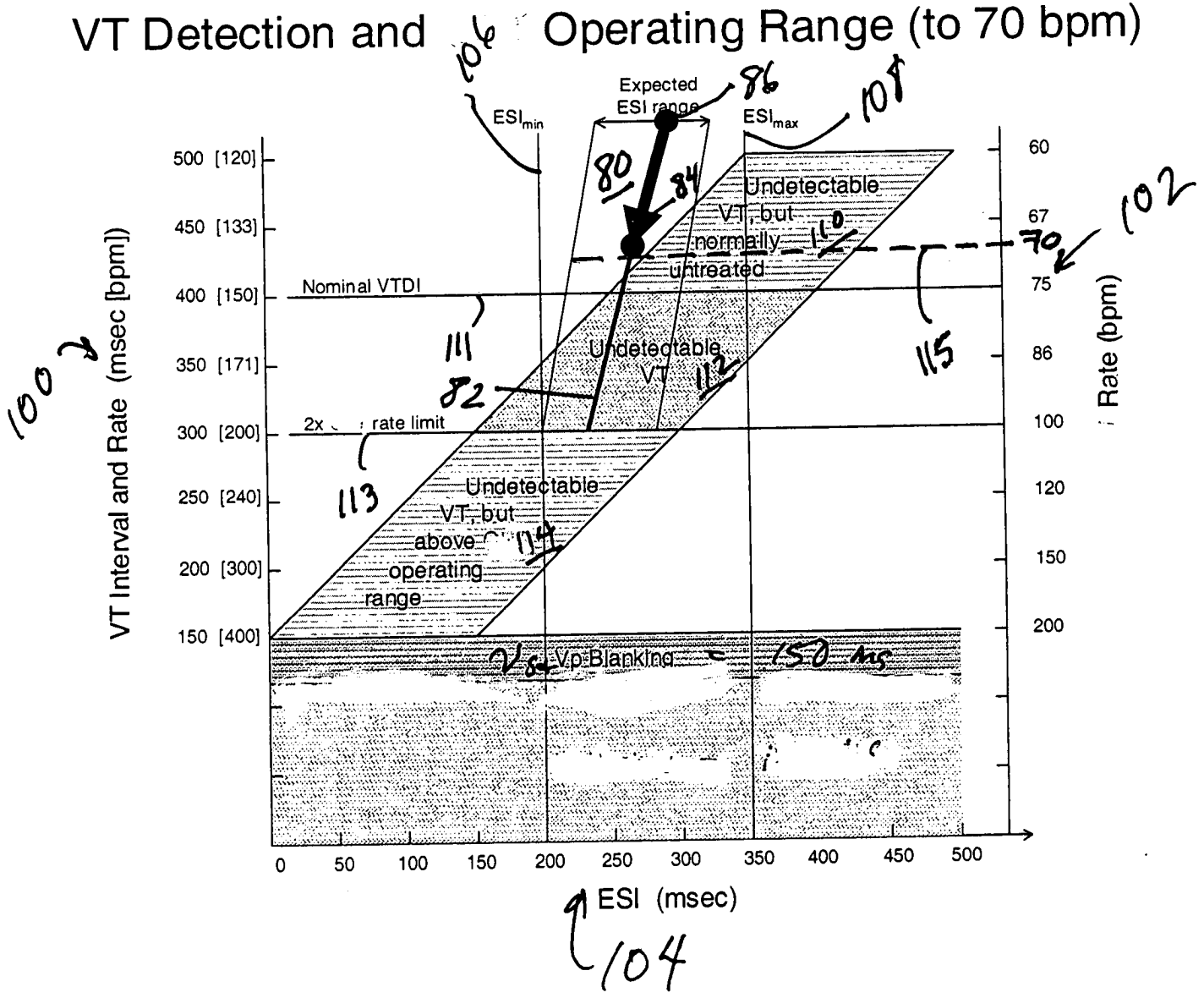

VT Detection and Operating Range (to 70 bpm)
106
Expected ESI range
86
ESI$_{min}$
ESI$_{max}$
108
80
84
Undetectable VT, but normally untreated
110
102
Nominal VTDI
111
115
Undetectable VT
112
82
2x rate limit
113
Undetectable VT, but above operating range
114
100
VT Interval and Rate (msec [bpm])
500 [120]
450 [133]
400 [150]
350 [171]
300 [200]
250 [240]
200 [300]
150 [400]
60
67
70
75
86
100
120
150
200
Rate (bpm)
Vp Blanking
150 ms
0
50
100
150
200
250
300
350
400
450
500
ESI (msec)
104

FIG. 9

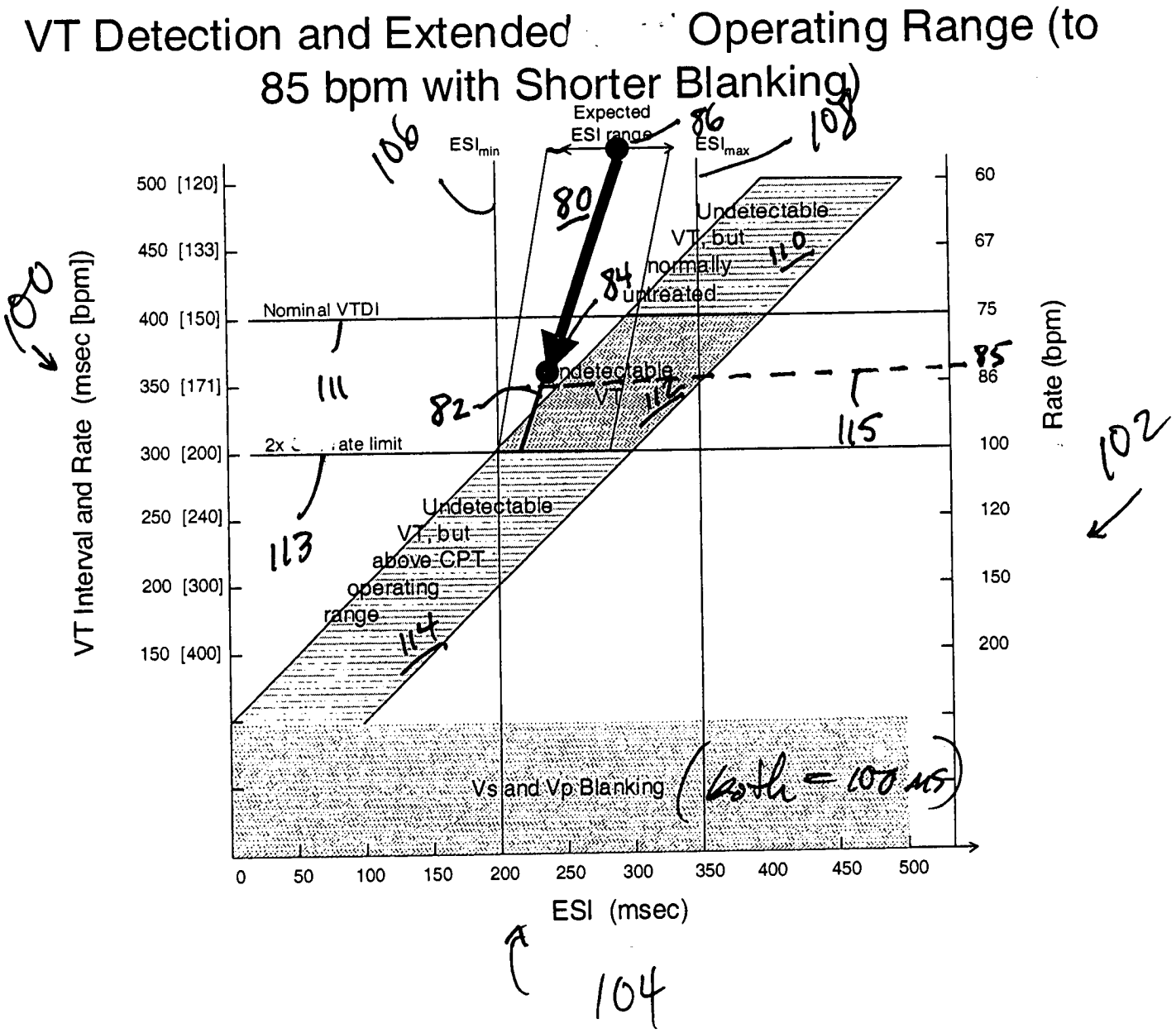

VT Detection and Extended Operating Range (to 85 bpm with Shorter Blanking)
Expected ESI range
ESI_min
ESI_max
Undetectable VT, but normally untreated
Nominal VTDI
Undetectable VT
2x [illegible] rate limit
Undetectable VT, but above CPT operating range
Vs and Vp Blanking
VT Interval and Rate (msec [bpm])
Rate (bpm)
ESI (msec)
500 [120]
450 [133]
400 [150]
350 [171]
300 [200]
250 [240]
200 [300]
150 [400]
60
67
75
86
100
120
150
200
0
50
100
150
200
250
300
350
400
450
500
106
108
86
80
84
110
111
82
112
115
85
113
114
100
102
104

FIG. 10

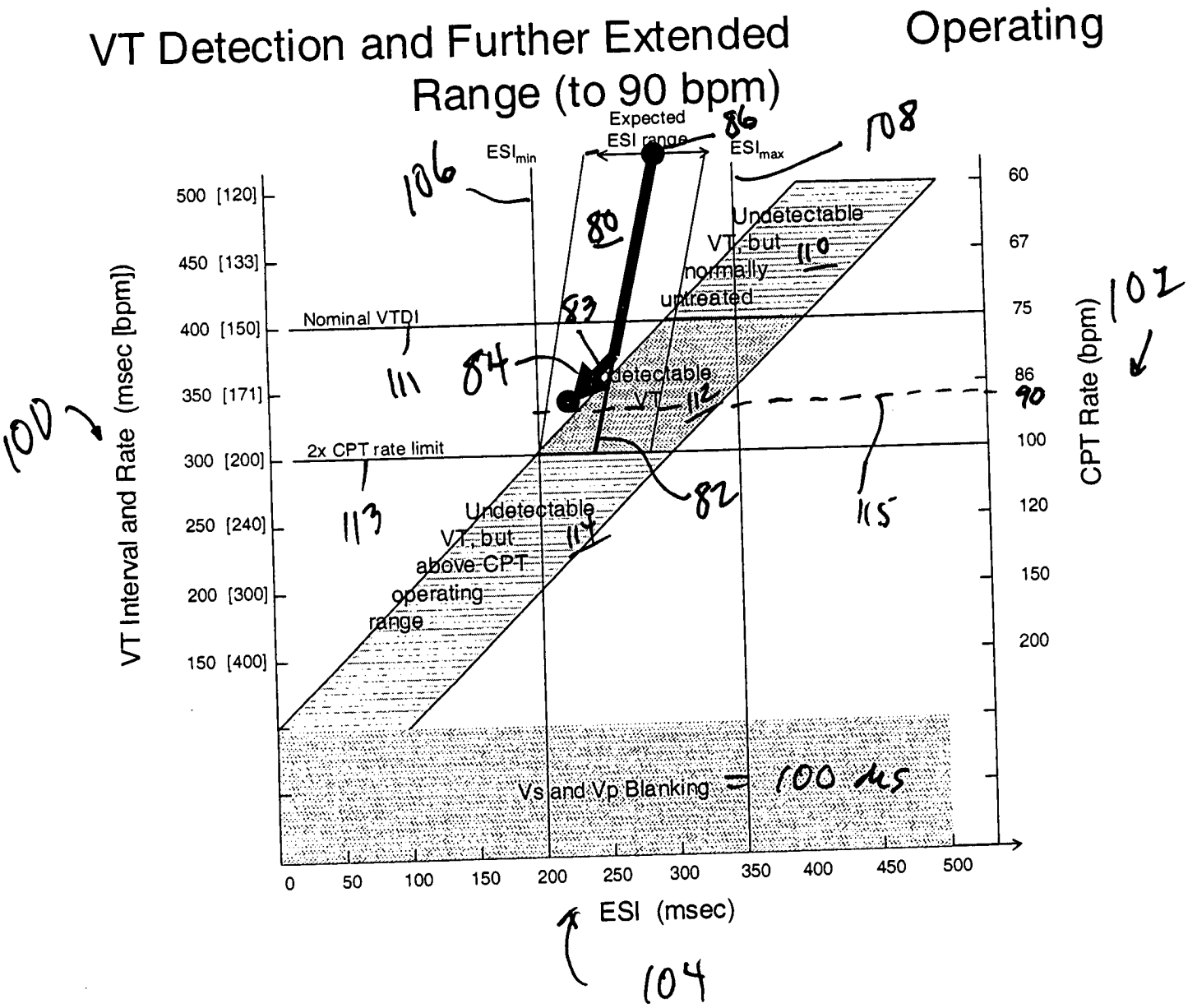

VT Detection and Further Extended Operating Range (to 90 bpm)
Expected ESI range
ESI$_{min}$
ESI$_{max}$
Undetectable VT, but normally untreated
Nominal VTDI
Undetectable VT
2x CPT rate limit
Undetectable VT, but above CPT operating range
Vs and Vp Blanking = 100 ms
VT Interval and Rate (msec [bpm])
CPT Rate (bpm)
ESI (msec)
500 [120]
450 [133]
400 [150]
350 [171]
300 [200]
250 [240]
200 [300]
150 [400]
60
67
75
86
90
100
120
150
200
0
50
100
150
200
250
300
350
400
450
500
100
102
104
106
108
110
111
112
113
114
115

FIG. 11

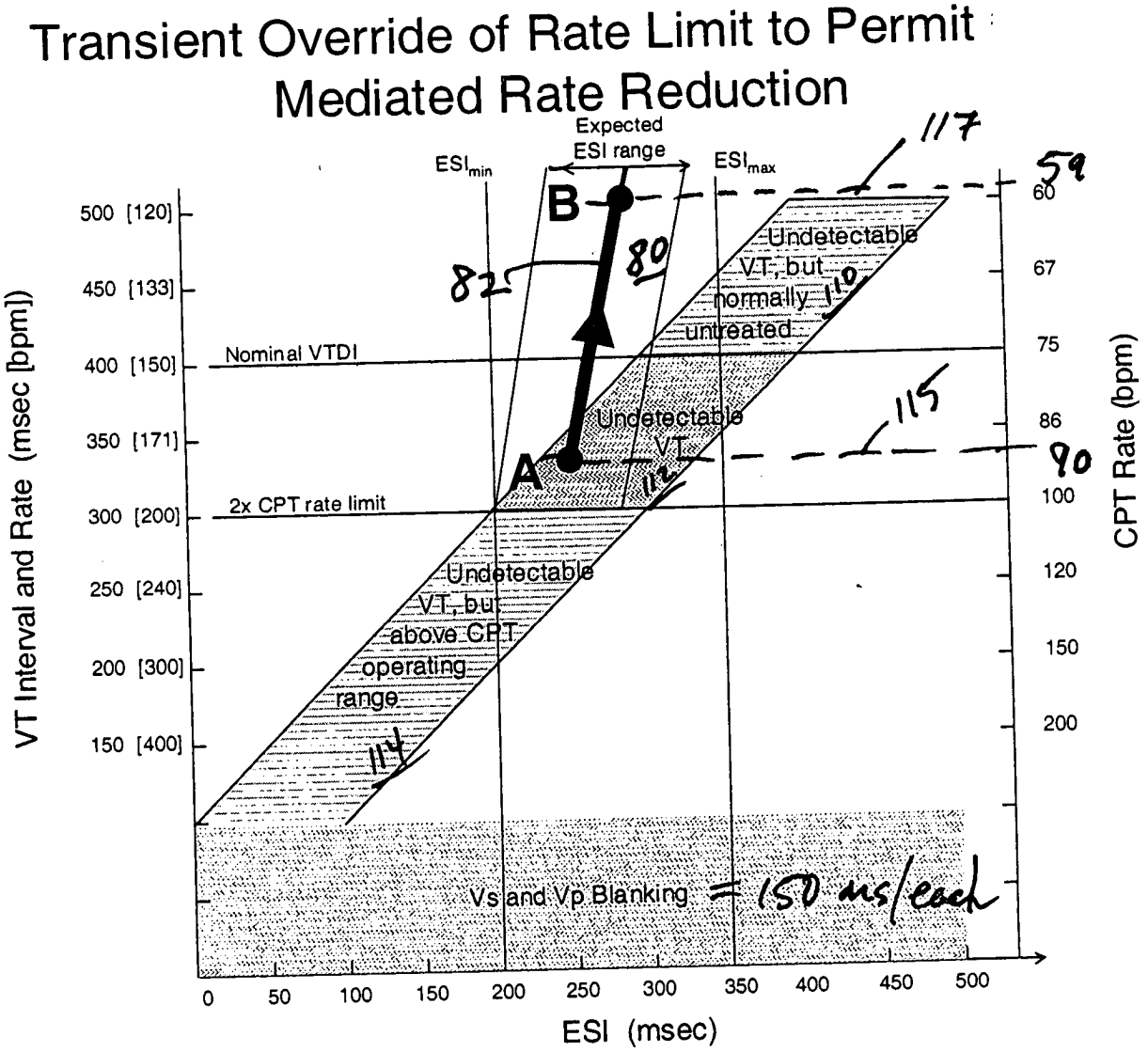
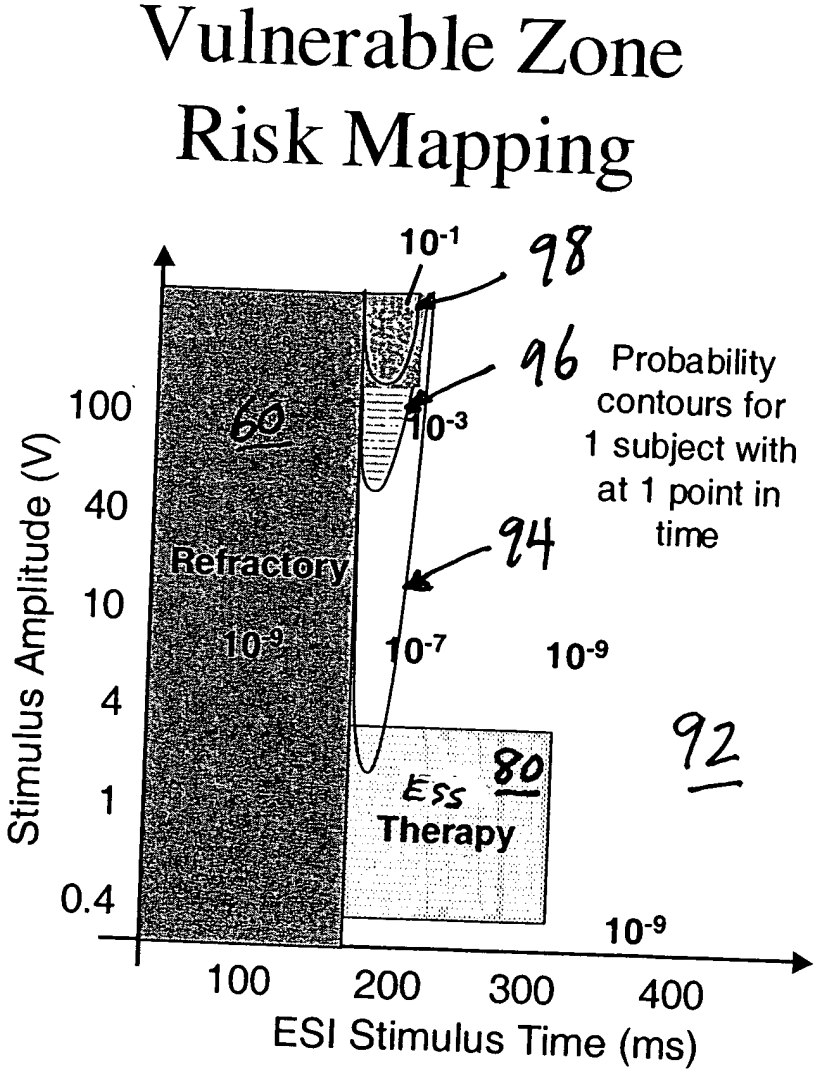

Transient Override of Rate Limit to Permit Mediated Rate Reduction
Expected ESI range
ESI min
ESI max
B
A
Undetectable VT, but normally untreated
Undetectable VT
Undetectable VT, but above CPT operating range
Nominal VTDI
2x CPT rate limit
Vs and Vp Blanking = 150 ms/each
VT Interval and Rate (msec [bpm])
CPT Rate (bpm)
ESI (msec)
500 [120]
450 [133]
400 [150]
350 [171]
300 [200]
250 [240]
200 [300]
150 [400]
60
67
75
86
100
120
150
200
0
50
100
150
200
250
300
350
400
450
500
117
59
82
80
110
115
90
114

FIG. 12


Vulnerable Zone
Risk Mapping
10^{-1}
98
96
Probability contours for 1 subject with at 1 point in time
10^{-3}
94
10^{-7}
10^{-9}
10^{-9}
92
80
ESS Therapy
60
Refractory
10^{-9}
10^{-9}
Stimulus Amplitude (V)
100
40
10
4
1
0.4
100
200
300
400
ESI Stimulus Time (ms)